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August 22, 2013

VIA FACSIMILE

The Honorable Mitchell S. Goldberg
7614 United States Courthouse
601 Market Street
Philadelphia, PA 19106

Re: *In re: Suboxone (Buprenorphine Hydrochloride and Nalaxone) Antitrust Litig.*, MDL No. 2445 (MSG) (E.D. Pa.)

Dear Judge Goldberg:

Direct Purchaser Class Plaintiffs and End-Payor Class Plaintiffs ("Plaintiffs") jointly write pursuant to Paragraph 6(b) of the Court's Pretrial Order Number 2 (Dkt No. 44), which directed Plaintiffs to submit a request for "limited discovery, as discussed at the August 1 status conference." During that status conference, the Court indicated that while discovery would be stayed pending the Court's ultimate decision on Reckitt's forthcoming motion to dismiss, Plaintiffs could submit a discrete list of categories of documents that could be produced by Reckitt readily, easily and without undue burden (*see* Tr. at 45:3-12) (Dkt No. 45), so that the parties would not remain idle during the pendency of the motion.[1]

Plaintiffs, broadly speaking, allege that Reckitt improperly maintained its monopoly over Suboxone by delaying and impeding competition from generic versions of its branded Suboxone Tablet product in at least three different ways: (1) changing the form of Suboxone from tablet to film (which is not superior in any form or fashion), and coercing the market switch from tablets to film in order to interfere with the automatic substitution of less-expensive generic versions of tablets for more expensive branded versions of tablets as normally occurs; (2) manipulating Single Shared Risk Evaluation and Mitigation Strategy (SSRS/REMS)[2] to block and/or delay approval of generic Suboxone tablets by, among other things, feigning cooperation with

[1] Pursuant to Pretrial Order Number 2, briefing on Defendant's motion to dismiss is set to conclude on November 15, 2013.
[2] The establishment of a SSRS/REMS was a prerequisite to FDA approval of generic tablets. *See* Plaintiffs' Consolidated Amended Complaint (Dkt No. 47) at ¶¶ 57-60, 98-112 ("Compl.").

prospective generic competitors in the development of a single, shared REMS program for both branded and generic Suboxone tablets (Compl. at ¶¶ 98-112); and (3) filing an objectively baseless Citizen Petition with the Food and Drug Administration ("FDA") to delay and/or impede approval of less-expensive generic Suboxone tablets (Compl. at ¶¶ 113-142).

As Plaintiffs indicated at the status conference, Plaintiffs believe there will be substantial overlap between the discovery required for each of these theories. *See* Tr. at 41:2-5. In accordance with the Court's instructions, each area sought is discrete and could be produced easily with little or no burden on Reckitt:

(1) All documents submitted to (or received from) FDA relating to Reckitt's 2012 Citizen's Petition.

(2) All documents submitted to (or received from) the Federal Trade Commission or any other State or Federal antitrust agency in connection with any investigation of Reckitt's conduct with respect to Suboxone, including but not limited to Civil Investigative Demands and documents produced in response thereto, document requests and/or interrogatories.

(3) Clinical studies (including internal reports and published studies) pertaining to the safety and/or efficacy of Suboxone tablets and film, including but not limited to studies comparing Suboxone film versus tablets and studies comparing the packaging of Suboxone film versus tablets (*i.e.,* bottles versus unit-dose packaging), including studies that compare the risk of pediatric exposure and/or diversion between tablets and film.

(4) All documents relating to Reckitt's creation and FDA approval of REMS and an SSRS for branded and generic versions of Suboxone film and tablets.

(5) Non-duplicative copies of Reckitt's marketing, advertising and/or promotional materials concerning Suboxone tablets and film that were published or distributed from August 1, 2010 to the present.

Should Defendants, in their forthcoming motion to dismiss, refer to facts that are outside Plaintiffs' complaint, Plaintiffs would like the opportunity to obtain the additional discovery necessary for Plaintiffs to respond.

Respectfully submitted,

Joseph Opper (KH)

Joseph Opper, Esq.

Liaison Counsel and Interim Co-Lead Counsel for Direct Purchaser Class Plaintiffs

Jeffrey L. Kodroff (KH)

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Liaison Counsel for Indirect Purchaser Class Plaintiffs

cc via electronic mail: All Counsel Listed in Paragraph 8 of Pretrial Order No. 2

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TO: Hon. Mitchell S. Goldberg FROM: Kimberly Hennings, Esq.

FIRM: U.S. District Court (E.D. Pa.) DATE: August 22, 2013

CITY/STATE: _____

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